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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,714	06/04/2007	Jane K. Relton	2681.0450001	2306

53644 7590 01/26/2012

STERNE, KESSLER, GOLDSTEIN & FOX, P.L.L.C.
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EXAMINER	
WEGERT, SANDRA L	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
01/26/2012	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,714	RELTON ET AL.	
	Examiner	Art Unit	
	SANDRA WEGERT	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1,3,4,6,10-12,19-24 and 26-36* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,3,4,6,10-12,19-24 and 26-36* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *28 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Status of Application, Amendments, and/or Claims

Upon further consideration, the last Office Action is hereby VACATED. A new Office Action follows:

A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. This application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid.

The amendment and Remarks, submitted 4 February 2011, have been entered and considered. The Declaration submitted under 37 C.F.R. § 1.132 has been entered and considered. Claims 1, 3, 4, 6, 10-12, 19-24 and 26-36 are pending. Claims 2, 5, 7-9, 13-18 and 25 have been cancelled. Claims 1, 3, 4, 23, 24, 26, 27 and 36 have been amended.

Claims 1, 3, 4, 6, 10-12, 19-24 and 26-36 are under examination in the Instant Application.

Withdrawn Claim Rejections/Objections

Claim Rejections: Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 22 and 23 on the grounds of nonstatutory obviousness-type double patenting over claims 103 and 104 of copending Application No. 2009/0215691 (serial No. 12/335,328), is *withdrawn*, based on claim amendments and cancelled claims in the co-pending application.

Claim Rejections - 35 USC § 112, first paragraph – Scope of Enablement and Enablement.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

The rejection of claims 1, 3, 4, 6, 10-12, 19-21, 24 and 26-34 under 35 USC § 112, first paragraph, for Breadth and Enablement, is withdrawn based on new grounds of rejection (see

below). Claims 22, 23, 35 and 36 *remain* rejected under 35 U.S.C. 112, first paragraph, for the **Deposit** rejection (see below).

Declaration under 37 C.F.R. § 1.132

Applicants have submitted a Declaration under 37 C.F.R. § 1.132 (Strittmatter, S.; 16 August 2011) that discusses the validity of using 6-OHDA and MPTP-lesioned rats, mice and monkeys as models of Parkinson's disease. They also cited several research papers that discuss toxin-induced models of PD (Fuxe and Ungerstedt, 1976, Pharmac. Ther. B. 2:41-47; Tolwani, R.J., et al., 1999, Lab. Animal Sci. 49:363-371; Betarbet, R., et al., 2002, BioEssays 24:308-318; and Deumens, R., et al., 2002, Exp. Neurology 175:303-317).

Applicants also assert that the 6-OHDA model of Parkinson's disease is useful in tests that explore dopaminergic neuronal regeneration.

Applicants' arguments concerning the evidence in the Strittmatter Declaration submitted under 37 C.F.R. § 1.132, are *moot* as to the instant rejections, as the Declaration addresses only the currently withdrawn Enablement rejection.

New Claim Rejections/Objections

Claim Rejections- 35 USC § 102

The following are quotations of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international

application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 3, 4, 6, 10-12, 19-24 and 26-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Benowitz, et al (2008, US Publication 2008/0274077; hereinafter "Benowitz"). The patent application's priority date is Dec. 13, 2003. Benowitz discloses the soluble form of mammalian NgR1, residues 26-344, and bearing 100% similarity to instant SEQ ID NO: 4 (see Appendix, below). The disclosure in Benowitz relates specifically to independent claims that recite "a soluble form of a mammalian NgR1" as well as claims that recite residues 26-344 of the NgR.

In Benowitz, antagonists of the NgR receptor are administered to mammals or human beings in order to stimulate axon regeneration (p. 1, Para 0003). Administration of the soluble receptor is mentioned specifically (Para 0016), while the peptides that make up the soluble domains, including or excluding the cytosolic anchor, are mentioned specifically as well (Para 0019). Administration to treat basal ganglionic degeneration -e.g., substantia nigra- is addressed at Paragraph 0025; specific striatal administration is also mention at Paragraph 0025 (line 4). Acute and chronic infusion of soluble NgR is recited in Paragraph 0126. Soluble fusion proteins made up of the soluble form of NgR and immunoglobulins are recited specifically in Paragraph 0040. An "Fc" domain as part of the fusion protein is mentioned in Paragraph 0040 (see "NgR(310)ecto-Fc"). Subjects include those with neuronal degeneration, including those with dopaminergic neurodegeneration (see the Parkinson's disease patient in Para 0025).

Therapeutically-effective dose ranges are given as about 0.001 to 30 mg/kg (Para 0059), encompassing the ranges cited in the instant claims. Benowitz also suggests that the method of

administering soluble NgR would be useful in patients with Parkinson's disease (Benowitz, claim 32). Benowitz discusses the use of antibodies made against NgR extensively (Para 0039), including the use of monoclonal antibodies (Para 0048) against antigens derived from NgR. The reference also teaches administration of NgR antagonists intracranially (Para 0124) and directly to the site of injury (Para 0125).

Deposit Information

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The invention appears to employ novel antibodies (i.e., hybridoma clones). Since the monoclonal antibodies are essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the antibodies are not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the hybridomas.

It is not clear from the disclosure that deposit of the disclosed hybridomas meets all the criteria set forth in MPEP 608/01 (p)(C), items 1-3, such as whether the depository is recognized and approved by the World Intellectual Property Organization (WIPO) (see MPEP § 2405).

The Assurance of compliance may be in the form of a declaration or averment under oath. A suggested format for such a declaration or averment is outlined below:

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restrictions on the availability to the public of the material will be irrevocably removed upon the granting of a patent.

5. States that the material has been deposited under conditions that ensure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 35 CFR 1.14 and 35 USC 122.

6. States that the deposited material will be stored with all care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the

furnishing of a sample of the deposited microorganism, and in any case at least thirty (30) years after the date of a deposit or for the enforceable life of the patent, whichever is longer.

7. Acknowledges the duty to replace the deposit should the depository be unable to furnish a sample when requested due to the condition of the deposit.

8. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

As a possible means of completing the record, applicants' representative may submit a copy of the deposit receipt.

Conclusion: Claims 1, 3, 4, 6, 10-12, 19-24 and 26-36 are rejected for the reasons recited above.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Nickol, can be reached at (571) 272-0835.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

/SLW/

12 December 2011

/Gary B. Nickol /

Supervisory Patent Examiner, Art Unit 1645

Appendix - Search Results

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RESULT 5
US-10-580-364-10
; Sequence 10, Application US/10580364
; Publication No. US20080274077A1
; GENERAL INFORMATION:
;  APPLICANT: CHILDREN'S MEDICAL CENTER CORPORATION
;  APPLICANT:  BENOWITZ, LARRY I.
;  APPLICANT:  FISCHER, DIETMAR
;  TITLE OF INVENTION: METHOD FOR TREATING NEUROLOGICAL DISORDERS
;  FILE REFERENCE: 701039-054381-PCT
;  CURRENT APPLICATION NUMBER: US/10/580,364
;  CURRENT FILING DATE:  2006-05-23
;  PRIOR APPLICATION NUMBER: PCT/US04/42255
;  PRIOR FILING DATE: 2004-12-10
;  PRIOR APPLICATION NUMBER: 60/529,833
;  PRIOR FILING DATE: 2003-12-16
;  NUMBER OF SEQ ID NOS: 18
;  SOFTWARE: PatentIn Ver. 3.3
; SEQ ID NO 10
;   LENGTH: 344
;   TYPE: PRT
;   ORGANISM: Homo sapiens
US-10-580-364-10

  Query Match             100.0%;  Score 1711;  DB 5;  Length 344;
  Best Local Similarity   100.0%;
  Matches  319;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps
0;

Qy          1 PCPGACVCYNEPKVTTSCPQQGLQAVPVGIPAASQRIFLHGNRISHVPAASFRACRNLTI 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         26 PCPGACVCYNEPKVTTSCPQQGLQAVPVGIPAASQRIFLHGNRISHVPAASFRACRNLTI 85

Qy         61 LWLHSNVLARIDAAAFTGLALLEQLDLSDNAQLRSVDPATFHGLGRLHTLHLDRCGLQEL
120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         86 LWLHSNVLARIDAAAFTGLALLEQLDLSDNAQLRSVDPATFHGLGRLHTLHLDRCGLQEL
145

Qy        121 GPGLFRGLAALQYLYLQDNALQALPDDTFRDLGNLTHLFLHGNRISSVPERAFRGLHSLD
180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        146 GPGLFRGLAALQYLYLQDNALQALPDDTFRDLGNLTHLFLHGNRISSVPERAFRGLHSLD
205

Qy        181 RLLLHQNRVAHVHPHAFRDLGRLMTLYLFANNLSALPTEALAPLRALQYLRLNDNPWVCD
240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Db        206 RLLLHQNRVAHVHPHAFRDLGRLMTLYLFANNLSALPTEALAPLRALQYLRLNDNPWVCD
265

Qy        241 CRARPLWAWLQKFRGSSSEVPCSLPQRLAGRDLKRLAANDLQGCAVATGPYHPIWTGRAT
300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        266 CRARPLWAWLQKFRGSSSEVPCSLPQRLAGRDLKRLAANDLQGCAVATGPYHPIWTGRAT
325

Qy        301 DEEPLGLPKCCQPDAADKA 319
              ||||||||||||||||||
Db        326 DEEPLGLPKCCQPDAADKA 344
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